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(54) Title: PRE-FORMED, SELF-ADHESIVE SHEET DEVICES SUITABLE FOR TOPICAL APPLICATION

(57) Abstract: A pre-formed, sheet device comprising (a) less than 10 % of a polysaccharide mixture consisting of (i) a red seaweed polysaccharide; (ii) a mannose containing polysaccharide selected from a galactomannan, glucomannan, and derivatives or mixtures thereof and; (iii) a fermentation polysaccharide, or derivatives thereof; and (b) form about 30 % to about 99.5 % of water; wherein the device comprises less than 10 % total polysaccharide. The pre-formed, sheet devices of the invention are suitable for topical application and display desirable amounts of syneresis and/or improved mechanical properties such as strength or flexibility, as well as excellent moisturisation, hydration and cooling benefits. Further, the devices of the present invention are easy to handle, unobtrusive and conform to the contours of a target surface when applied.

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one embodiment describes a method of preparation of a gel patch whereby the patch requires formation *in-situ* on the skin, making it messy to apply. EP-B-309,309 describes a dry patch which requires the skin to be moistened or the patch wetted so that it hydrates and adheres to the skin. Conversely, other patches or devices may be too wet or sticky, as the gelling agents comprising the patch or device may not form a solid gel structure and as a result, the patches or devices are difficult to handle and apply to the skin.

Some patches or devices are too dry, or are inflexible and therefore do not conform well to the contours of the surface to which they are applied. Alternatively, others may be strongly adhesive, tight and uncomfortable to wear and remove, and many patches may not provide an effective release and penetration of benefit agents.

Polysaccharide compositions are known for use in self adhesive patches or devices. For example EP-A-682 938, WO96/25923, EP-A-750905, WO98/17263, EP-A-850649, EP-A-674913 and WO84/02466 disclose various polysaccharides which may be useful in an adhesive patch or device. Additionally, many of the adhesive patches or devices described in the aforementioned documents optionally comprise cosmetic or therapeutic actives.

GB 1,341,999 discloses a gelled medium suitable for treating burns comprising a liquid phase, a burn treating agent and an amount of a gel former. The gelled medium is described as being flexible and having an essentially dry, continuous, non-adhesive surface and plasticity so as to conform to the body. A preferred gel former is disclosed as a combination of xanthan and locust bean gum. The examples also disclose a burn treating antiseptic pad comprising agarose, water and silver nitrate. The document discusses that a slight amount of syneresis in the gelled medium is helpful in wetting the surface with the burn treating substance and for ease in removal of the medium from a mould.

JP-B2-276 1936 discloses aqueous sheet-like pack agents comprising xanthan gum and locust bean gum in combination with a water-soluble solvent. The sheet-like pack agents of the invention are disclosed as having excellent shape retention properties at high temperature, providing a moist feel and having a high skin moisturising effect. The examples disclose that the pack agents may further comprise 0.1% of a skin beautifying component.

EP-A-161 681 discloses gel plates comprising a polysaccharide and an aqueous solution of a polyhydric alcohol. Preferred polysaccharides for the gel plates described therein are a blend of carrageenan and a galactomannan, or carrageenan alone. The compositions optionally comprise medical components such as skin stimulants, antiphlogistics, analgesics and antibiotics. The gel plates are disclosed as transparent or inconspicuous,

desirable amount of syneresis so as to provide a patch or device which is self adhesive and which effectively releases the ingredients comprised within the polysaccharide matrices such as benefit agents and water to deliver in-use hydration, moisturisation or treatment benefits.

- 5 It has now been surprisingly found that less than 10% of an aqueous polysaccharide mixture consisting of a red seaweed polysaccharide; a mannose containing polysaccharide, or mixtures thereof; and a fermentation polysaccharide or derivatives thereof, provides a pre-formed, sheet device with excellent in-use characteristics, and improved syneresis, and/or mechanical properties. Devices comprising the
- 10 aforementioned aqueous polysaccharide mixture form a self supporting, sheet device which has a high flexibility to conform to the contours of the skin, hair or nails, is thin, yet forms a high strength structure which is easy to handle and apply to the target surface. The aqueous polysaccharide mixture is selected to further provide the pre-formed, sheet device with a desirable amount of syneresis.

15 Summary of the Invention

The present invention relates to a pre-formed, sheet device comprising;

- (a) less than 10% of a polysaccharide mixture consisting of;
  - (i) a red seaweed polysaccharide;
  - (ii) a mannose containing polysaccharide selected from a galactomannan, glucomannan, and derivatives or mixtures thereof and;
  - (iii) a fermentation polysaccharide, or derivatives thereof; and
- (b) from about 30% to about 99.5% of water;

wherein the device comprises less than 10% total polysaccharide.

- The pre-formed, sheet devices of the present invention show a desirable amount of syneresis, as well as providing excellent in-use characteristics such as unobtrusiveness, ease of handling, conformability, hydration, moisturisation and cooling benefits upon topical application. Further, the pre-formed, sheet devices of the present invention have
- 20 excellent mechanical properties and form a high strength structure from a thin aqueous polysaccharide mixture which has a degree of elasticity and is flexible.

According to a second aspect of the present invention there is provided a cosmetic method of treatment comprising applying to the skin, hair or nails a pre-formed, sheet device.

of its volume such that ingredients bound within the gel matrices such as water or benefit agents, are released towards, and penetrate the target area.

The term "polysaccharide" as used herein, means a naturally occurring or synthetically produced, linear or branched polymer of monosaccharide units, which swells when dispersed in water at low dry concentrations and gels the aqueous phase.

The term "non-occlusive" as used herein, means that the pre-formed, sheet device as so described does not substantially block the passage of air and moisture through the surface of the skin, hair or nails.

The present pre-formed, sheet devices are suitable for topical application to the skin, hair or nails.

#### Polysaccharide Mixture

As an essential component of the pre-formed, sheet devices described herein, the devices comprise a specified polysaccharide mixture.

The polysaccharide mixture of the present invention forms a self-adhesive, sheet device which is self-supporting. Optionally, in order to improve the integrity of the device, an occlusive or non-occlusive backing material, often referred to as a "substrate" may be employed as an adjunct to the device. In order to impart added strength to the pre-formed, sheet devices, substances which act as gel strengthening agents such as mono- or multi-valent salts may be incorporated into the polysaccharide mixture. Suitable cations for the mono- or multi- valent salts may be selected from potassium, sodium, ammonium, zinc, aluminium, calcium and magnesium ions, or mixtures thereof. Suitable anions associated with the aforementioned cations may be selected from chloride, citrates, sulfate, carbonate, borate and phosphate anions, or mixtures thereof.

It has been found that specific blends of polysaccharides in combination with water, form gels having desirable aesthetics and in-use characteristics. Further, the polysaccharides of the mixture of the present invention, may be combined together at various percentages or ratios to modify the physical characteristics of the pre-formed, sheet devices. The polysaccharide mixture herein provides improved syneresis, or mechanical properties, such as flexibility or strength, from the aqueous, pre-formed, sheet device. In a preferred embodiment, the polysaccharide mixture of the present invention improves the flexibility, strength, and syneresis of a pre-formed, sheet device.

The pre-formed, sheet devices of the present invention comprise less than 10% total polysaccharide. In general, the pre-formed, sheet devices of the present invention preferably comprise less than 10%, more preferably less than 5% and especially less than

carrageenan are greatly influenced by potassium ions and those of iota-carrageenan by calcium ions.

On the other hand, agar, an electrically neutral galactan having a high anhydrogalactose content, gels independently of the addition of cations. Kappa-carrageenan has the highest  
5 anhydrogalactose content and the lowest sulfate content among the carrageenans and as a result has the most powerful gel-forming properties.

Galactomannan: Galactomannans are vegetable reserve polysaccharides which occur in the endosperm cells of numerous seeds of *Leguminosae*. The collective term "galactomannan" comprises all polysaccharides which are built up of galactose and  
10 mannose residues. Galactomannans are mannose containing polysaccharides as they comprise a linear backbone of (1→4)-linked  $\beta$ -D-mannopyranosyl units. To these rings are attached as branches, isolated galactopyranose residues by  $\alpha$ -(1,6)-glucoside bonds. Galactomannans may in addition also contain minor amounts of other sugar residues. Suitable galactomannans for use herein are fenugreek gum; lucern; clover; locust bean  
15 gum known for example in the industry under the (CTFA) trade designation as carob bean gum, commercially available as "Seagul L" from FMC (Philadelphia, PA, USA); tara gum commercially available from Starlight Products (Rouen, France) or Bunge Foods (Atlanta, GA, USA); guar gum derived from the ground endosperms of *Cyamopsis tetragonolobus*, commercially available as "Burtonite V7E" from TIC Gums (Belcamp,  
20 MD, USA), "Jaguar C" from Rhone-Poulenc (Marietta, GA, USA), or "Supercol" from Aqualon (Wilmington, DE, USA); and cassia gum commercially available from Starlight Products (Rouen, France), or mixtures thereof. Preferably, the galactomannans for use herein, have on average one of every 1 to about 5 mannosyl units substituted with a (1→6)-linked- $\alpha$ -D-galactopyranosyl unit and are selected from guar gum, locust bean  
25 gum and cassia gum, or mixtures thereof.

Glucomannan: Glucomannans are mannose containing polysaccharides which comprise an essentially linear backbone of  $\beta$  (1→4)-linked glucose and mannose residues. The C-6 position of a mannose or glucose residue in the polysaccharide backbone may be substituted with an acetyl group. The acetyl groups are generally found on one per six  
30 sugar residues to one per twenty sugar residues. Suitable glucomannans or derivatives thereof for use herein have a ratio of mannose to glucose of from about 0.2 to about 3. Preferred glucomannans for use herein include konjac mannan, which is the generic name for the flour formed from grinding the tuber root of the *Amorphophallus konjac* plant (elephant yam), commercially available under the trade name "Nutricol® konjac flour"

In a preferred embodiment, the polysaccharide mixture comprises a mannose containing polysaccharide which is a mixture of a galactomannan and glucomannan or derivatives thereof.

5 It is believed that in polysaccharide mixtures, comprising either a glucomannan and/or a galactomannan, the mannose containing polysaccharides complement the red seaweed polysaccharide. This synergy is believed to arise due to the interactions between the polysaccharides. Red seaweed polysaccharides form double helical structures whereas glucomannans and galactomannans have areas of relative un-substitution on the polymer backbone. These areas of relative un-substitution on the polymer backbone interact with  
10 the helices of the red seaweed polysaccharides and contribute to the mechanical strength and flexibility of the pre-formed, sheet devices of the present invention.

All gels undergo syneresis, as herein before defined, to some degree. Syneresis provides a mechanism for the delivery of a benefit agent to a target area. The liquid layer exuded onto the surface of the coherent gel phase is readily available for diffusion, facilitating a  
15 short wear time of the device. The pre-formed, sheet devices of the present invention desirably display a moderate amount of syneresis and preferably, the devices herein are moist to the touch. A moderate amount of syneresis is seen by the present inventors as a highly desirable property of a device comprising the polysaccharide mixture as the liquid exuded onto the surface of the gelled device facilitates its adhesion to a target surface thus  
20 obviating the need for either an additional adhesive overlaying the gelled form or an adhesive coated substrate. By comparison, if a gelled device exhibits too little syneresis, the device although wetting an area, is not likely to provide good adhesion to the target area, whilst an excessive amount of syneresis results in an ineffective and unattractive product.

25 From the viewpoint of providing improved syneresis and mechanical properties from a pre-formed, sheet device, preferably in the polysaccharide mixture, the ratio of red seaweed polysaccharide to mannose containing polysaccharide is from about 20:1 to about 1:5 and more preferably from about 7:1 to about 1:2.

#### Water

30 A further essential ingredient of a pre-formed, sheet device of the present invention is water. The total water content of a pre-formed, sheet device of the present invention is from about 30% to about 99.5%, preferably from about 40% to about 95%, more preferably from about 50% to about 85% by weight of the device.

Synthetic fibers useful in the present invention include acetate fibers, acrylic fibers, cellulose ester fibers, modacrylic fibers, polyamide fibers, polyester fibers, polyolefin fibers, polyvinyl alcohol fibers, rayon fibers, polyurethane foam, and mixtures thereof. Specific examples of some of these synthetic fibers and other suitable fibres and non  
5 woven materials prepared therefrom are described in WO98/18444, incorporated herein by reference, and include acrylics such as acrilan, creslan, and the acrylonitrile-based fiber, orlon; cellulose ester fibers such as cellulose acetate, arnel, and acele; and polyamides such as nylons (e.g., nylon 6, nylon 66, nylon 610, and the like).

Methods of making nonwoven materials are well known in the art and are described  
10 generally in WO98/18444, which is incorporated herein by reference. In the present invention the nonwoven layer can be prepared by a variety of processes including hydroentanglement, air entanglement, thermally bonding or thermo-bonding, and combinations of these processes. Moreover, the substrates of the present invention can consist of a single layer or multiple layers. In addition, a multilayered substrate can  
15 include films and other nonfibrous materials.

Nonwoven materials made from synthetic fibers useful in the present invention can also be obtained from a wide variety of commercial sources. Examples of suitable nonwoven layer materials useful herein are described in WO98/18444 and include HEF 40-047, an apertured hydroentangled material containing about 50% rayon and 50% polyester, and  
20 having a basis weight of about 51 grams per square metre (gsm), available from Veratec, Inc., Walpole, MA; ; Novonet<sup>R</sup> 149-616, a thermo-bonded grid patterned material containing about 100% polypropylene, and having a basis weight of about 60 gsm, available from Veratec, Inc., Walpole, MA; and HEF Nubtex<sup>R</sup> 149-801, a nubbed, apertured hydroentangled material, containing about 100% polyester, and having a basis  
25 weight of about 84 gsm, available from Veratec, Inc. Walpole, MA.

Paper substrates made from natural materials consist of webs or sheets most commonly formed on a fine wire screen from a liquid suspension of the fibers. See C.A. Hampel et al., The Encyclopedia of Chemistry, third edition, 1973, pp. 793-795 (1973); The Encyclopedia Americana, vol. 21, pp. 376-383 (1984); and G.A. Smook, Handbook of  
30 Pulp and Paper Technologies, Technical Association for the Pulp and Paper Industry (1986); which are incorporated by reference herein in their entirety. Paper substrates made from natural materials useful in the present invention can be obtained from a wide variety of commercial sources. Suitable commercially available paper substrates useful herein include "Kimwipes EX-L" available from Kimberley-Clark Corp., Roswell, GA, USA;  
35 Airtex<sup>R</sup>, an embossed airlaid cellulosic layer having a base weight of about 85 gsm, available from James River, Green Bay, WI; and Walkisoft<sup>R</sup>, an embossed airlaid

The substrate may also be a polymeric porous foam as described in US-A-5,260,345, to DesMarais, et al., issued Nov. 9, 1993, and US-A-4,394,930, to Koroman, issued July 26, 1983, incorporated herein by reference. Polymeric foams can in general be characterized as the structures which result when a relatively monomer-free gas or relatively monomer-free liquid is dispersed as bubbles in a polymerizable monomer-containing liquid, followed by polymerization of the polymerizable monomers in the monomer-containing liquid which surrounds the bubbles. The resulting polymerized dispersion can be in the form of a porous solidified structure which is an aggregate of cells, the boundaries or walls of which cells comprise solid polymerized material. The cells themselves contain the relatively monomer-free gas or relatively monomer-free liquid which, prior to polymerization, had formed the "bubbles" in the liquid dispersion. Specifically, soft, flexible, microporous (open or closed-cell) foam materials having surface hydrophilicity and fluid retention characteristics are particularly suitable for this application. Examples of polymeric foam materials are those prepared by polymerizing a particular type of water-in-oil emulsion. Such an emulsion is formed from a relatively small amount of a polymerizable monomer-containing oil phase and a relatively larger amount of a relatively monomer-free water phase. The relatively monomer-free, discontinuous "internal" water phase thus forms the dispersed "bubbles" surrounded by the continuous polymerizable monomer-containing oil phase. Subsequent polymerization of the monomers in the continuous oil phase forms the cellular foam structure. The aqueous liquid remaining in the foam structure formed upon polymerization can be removed by pressing and/or drying the foam. This type of polymerisation emulsion in general is known in the art as a high internal phase emulsion or "HIPE" foam.

Polymeric porous foams, including the foams prepared from the water-in-oil emulsions herein, may be relatively closed-celled or relatively open-celled in character, depending upon whether and/or the extent to which, the cell walls or boundaries, i.e., the cell windows, are filled or taken up with polymeric material. The polymeric porous foams useful in the present invention are those which are relatively open-celled in that the individual cells of the foam are for the most part not completely isolated from each other by polymeric material of the cell walls. Thus the cells in such substantially open-celled foam structures have intercellular openings or "windows" which are large enough to permit ready fluid transfer from one cell to the other within the foam structure.

In substantially open-celled structures of the type useful herein the foam will generally have a reticulated character with the individual cells being defined by a plurality of mutually connected, three dimensionally branched webs. The strands of polymeric material which make up the branched webs of the open-cell foam structure can be referred



The substrate can be made into a wide variety of shapes and forms including flat pads, thick pads, thin sheets, and having sizes ranging from a surface area of about 0.25 cm<sup>2</sup> to about 1,000 cm<sup>2</sup>. The exact size and shape will depend upon the desired use and product characteristics. Especially convenient are shapes which are designed to fit comfortably and conveniently to the users face, neck, hands, feet, and other parts of the body. These shapes may be square, circular, triangular, rectangular, oval, or other shapes which are composites of these such as shapes that could be described as "pickle", "butterfly", "moon", "semi-circle", "donut", or others.

The substrates of the present invention can comprise two or more layers, each having different textures. The differing textures can result from the use of different combinations of materials or from the use of different manufacturing processes or a combination thereof. In addition, separate layers of the substrate can be manufactured to have different colors, thereby helping the user to further distinguish the surfaces.

#### Benefit Agents

In a further preferred embodiment of the present invention, the pre-formed, sheet devices herein comprise a safe and effective amount of one or more benefit agents.

The term "safe and effective amount" as used herein, means an amount of a benefit agent high enough to modify the condition to be treated or to deliver the desired skin, hair or nail benefit, but low enough to avoid serious side effects, at a reasonable benefit to risk ratio within the scope of sound medical judgement. What is a safe and effective amount of the benefit agent will vary with the specific agent, the ability of the agent to penetrate through the skin, into, or onto the hair and/or nails, the user's age, the user's health condition, and the condition of the skin, hair or nails of the user, and other like factors.

The benefit agents include their pharmaceutically-acceptable salts and by "pharmaceutically-acceptable salts" are meant any of the commonly-used salts that are suitable for use in contact with the tissues of humans without undue toxicity, irritation, incompatibility, instability, irritation, allergic response, and the like.

In general, the pre-formed, sheet devices of the present invention comprise from about 0.01% to about 40%, preferably from about 0.05% to about 30% and most preferably from about 0.1% to about 20% by weight of the device of at least one benefit agent, or mixtures thereof.

The benefit agents useful herein can be categorised by their therapeutic benefit or their postulated mode of action. However, it is to be understood that the benefit agents useful herein can in some instances provide more than one therapeutic benefit or operate via

salicylic acid, serine, skull cap extract, siber hegner extract, siberian saxifrage extract, silicol, sodium lauryl sulfate, sodium sulfoacetamide, SOPHORA EXTRACT (available from Maruzen located in Morristown, NJ), sorbic acid, sulfur, sunder vati extract, tea tree oil, tetra hydroabietic acid, threonine, thyme extract, tioxolone, tocopherol and its esters, trehalose 6-undecylenoate, 3-tridecene-2-ol, triclosan, tropolone, UNITRIENOL T27 (available from Unichem, located in Chicago, IL), vitamin D<sub>3</sub> and its analogs, white thyme oil, willow bark extract, wogonin, ylang ylang, zinc glycerolate, zinc linoleate, zinc oxide, zinc pyrithione, zinc sulfate, zwitterionic surfactants (e.g., cetyl dimethyl betaine) and mixtures thereof.

- 10 Non-Steroidal Anti-Inflammatory Actives (NSAIDS): Examples of suitable NSAIDS and their esters for use herein are described in WO98/18444, incorporated herein by reference. Further non-limiting examples of non-steroidal anti-inflammatory drugs (NSAIDS) include flufenamic acid; panthenol and ether and ester derivatives thereof e.g. panthenol ethyl ether, panthenyl triacetate; pantothenic acid and salt and ester derivatives thereof, especially calcium pantothenate; aloe vera, bisabolol, allantoin and compounds of the liquorice (the plant genus/species Glycyrrhiza glabra) family, including glycyrrhetic acid, glycyrrhizic acid, and derivatives thereof e.g. salts such as ammonium glycyrrhizinate and esters such as stearyl glycyrrhetinate.

20 Topical Anaesthetics: Examples of suitable topical anaesthetic drugs for use herein are benzocaine and bupivacaine. Further suitable examples are described in WO98/18444, incorporated herein by reference.

25 Artificial Tanning Agents and Accelerators: Artificial tanning agents can help in simulating a natural suntan by increasing melanin in the skin or by producing the appearance of increased melanin in the skin. Non-limiting examples of artificial tanning agents and accelerators include glucose tyrosinate and acetyl tyrosine, brazilin, caffeine, coffee extracts, DNA fragments, isobutyl methyl xanthine, methyl xanthine, PHOTOTAN (available from Laboratoires Serobiologiques located in Somerville, NJ), prostaglandins, tea extracts, theophylline, UNIPERTAN P2002 (available from Unichem, located in Chicago, IL) and UNIPERTAN P27 (available from Unichem, located in Chicago, IL); and mixtures thereof. Further useful artificial tanning agents herein are described in WO98/18444.

Antiseptics: Examples of suitable antiseptics for use herein include alcohols, benzoate, sorbic acid, and mixtures thereof.

35 Anti-microbial and Anti-fungal Actives: Anti-microbial and anti-fungal actives can be effective to prevent the proliferation and growth of bacteria and fungi. Non-limiting

or colour. Non-limiting examples of skin soothing agents include absinthium, acacia, aescin, alder buckthorn extract, allantoin, aloe, APT (available from Centerchem, located in Stamford, CT), arnica, astragalus, astragalus root extract, azulene, BAICALIN SR 15 (available from Barnet Products Dist. Located in Englewood, NJ), baikal skullcap, baizhu, 5 balsam canada, bee pollen, BIOPHYTEX (available from Laboratories Serobiologiques, located in Somerville, NJ), bisabolol, black cohosh, black cohosh extract, blue cohosh, blue cohosh extract, boneset, borage, borage oil, borage seed oil, bromelain, calendula, calendula extract, CANADIAN WILLOWBARK EXTRACT (available from Fytokem), candelilla wax, cangzhu, canola phytosterols, capsicum, carboxypeptidase, celery seed, 10 celery stem extract, CENTAURIUM (available from Sederma, located in Brooklyn, NY), centaury extract, chamazulene, chamomile, chamomile extract, chaparral, chaste tree, chaste tree extract, chickweed, chicory root, chicory root extract, chirata, chishao, collodial oatmeal, comfrey, comfrey extract, CROMIST CM GLUCAN (available from Croda, located in Parsippany, NJ), darutoside, dehurian angelica, DEVIL'S CLAW 15 (available from MMP located in Plainfield, NJ), divalent metals (such as magnesium, strontium, manganese), doggrass, dogwood, EASHAVE (available from Pentapharm, located in Basel, Switzerland), eleuthero, ELHIBIN (available from Pentapharm, located in Basel, Switzerland), ENTELINE 2 (available from Secma, located in Pontrieux, France), ephedra, epimedium, esculoside, evening primrose, eyebright, EXTRACT LE- 20 100 (available from Sino Lion, located in World Trade Centre, NY), fangfeng, feverfew, ficin, forsythia fruit, ganoderma, gaoben, GATULINE A (available from Gattefosse, located in Saint Priest, France), gentian, germanium extract, ginkgo bilboa, ginkgo, ginseng extract, goldenseal, gorgonian extract, gotu kola, grape fruit extract, guaiac wood oil, guggal extract, helenalin esters, henna, honeysuckle flower, horehound extract, 25 horsechestnut, horsetail, huzhang, hypericum, ichthyol, immortelle, ipecac, job's tears, jujube, kola extract, LANACHRYS 28 (available from Lana Tech, located in Paris, France), lemon oil, lianqiao, licorice root, ligusticum, ligustrum, lovage root, luffa, mace, magnolia flower, manjistha extract, margaspidin, margaspidin, matricin, MICROAT IRC (available from Nurture, located in Missoula, MT) mints, mistletoe, MODULENE 30 (available from Seporga, located in Sophia Antipolis, France), mung bean extract, musk, oat extract, orange, panthenol, papain, peony bark, peony root, PHYTOPLENOLIN (available from Bio Botanica, located in Hauppauge, NY), PREREGEN (available from Pentapharm, located in Basel, Switzerland), purslane, QUENCH T (available from Centerchem, located in Stamford, CT), quillaia, red sage, rehmannia, rhubarb, rosemary, 35 rosmarinic acid, royal jelly, rue, rutin, sandalwood, sanqi, sarsaparilla, saw palmetto, SENSILINE (available from Silab, located in Brive, France), SIEGESBECKIA (available

located in Englewood, NJ), PHYTOSPHINGOSINE (available from Gist Brocades, located in King of Prussia, PA), PSENDOPILAGGRIN (available from Brooks Industries, located in South Plainfield, NJ), QUESTAMIDE H (available from Quest, located in Ashford, England), serine, stigmasterol, sitosterol, stigmastanol, soybean  
 5 derived sterols, sphingosine, s-lactoyl glutathione, stearic acid, SUPER STEROL ESTERS (available from Croda, located in Parsippany, NJ), thioctic acid, THSC CERAMIDE OIL (available from Campo Research, located in Raffles Quay, Singapore), trimethyl glycine, tocopheryl nicotinate, vitamin D3 and analogs or derivatives thereof, and Y2 (available from Ocean Pharmaceutical), or mixtures thereof.

10 Anti-Wrinkle and Anti-Skin Atrophy Actives: Anti-wrinkle and anti-skin atrophy actives can be effective in replenishing or rejuvenating the epidermal and/or dermal layer. These actives generally provide these desirable skin care benefits by promoting or maintaining the natural process of desquamation and/or building skin matrix components (e.g., collagen and glycosaminoglycans). Non-limiting examples of anti-wrinkle and anti-skin  
 15 atrophy actives include nicotinic acid and its esters, nicotiny alcohol, estrogens and estrogenic compounds, or mixtures thereof. Further suitable anti-wrinkle and anti-skin atrophy actives useful herein are described in WO98/18444.

Skin Repair Actives: Skin repair actives can be effective in repairing the epidermal and/or dermal layer. Non-limiting examples of skin repair actives include actein 27 - deoxyactein  
 20 cimidifugoside (cimigoside), adapalene, tazarotene, ademethionine, adenosine, aletris extract, aloe derived lectins, 3-aminopropyl dihydrogen phosphate, AMADORINE (available from Barnet Products, located in Englewood, NJ), anise extracts, AOSINE (available from Secma, located in Pontrieux, France), arginine amino benzoate, ASC III (available from E. Merck, located in Darmstadt, Germany), ascorbic acid, ascorbyl  
 25 palmitate, asiatic acid, asiaticosides, ARLAMOL GEO (available from ICI, located in Wilmington, DE), azaleic acid, benzoic acid derivatives, bertholletia extracts, betulinic acid, BIOCHANIN A, BIOPEPTIDE CL (available from Sederma, located in Brooklyn, NY) BIOPEPTIDE EL (available from Sederma, located in Brooklyn, NY), biotin, blackberry bark extract, blackberry lily extracts, black cohosh extract, blue cohosh extract,  
 30 butanoyl betulinic acid, catecholamines, chalcones, chaste tree extract, cis retinoic acid, citric acid esters, clover extracts, coenzyme Q10 (ubiquinone), coumestrol, CPC PEPTIDE (Barnet Products, located in Englewood, NJ), daidzein, dang gui extract, darutoside, debromo laurinterol, 1-decanoyl-glycero-phosphonic acid, dehydrocholesterol, dehydrodicreosol, dehydrodieugenol, dehydroepiandrosterone, DERMOLECTINE  
 35 (available from Sederma, located in Brooklyn, NY), dehydroascorbic acid, dehydroepiandrosterone sulfate, dianethole, 2,4-dihydroxybenzoic acid, diosgenin,

tricholine citrate, trifoside, uracil derivatives, ursolic acid, vitamin D<sub>3</sub> and its analogs, vitamin K, vitex extract, yam extract, yamogenin, and zeatin, or mixtures thereof.

Lipids: Examples of suitable lipids include cetyl ricinoleate, cholesterol hydroxystearate, cholesterol isostearate, CREMEROL (available from Amerchol, located in Edison, NJ),  
5 ELDEW C1301 (available from Ajinomoto, located in Teaneck, NJ), lanolin, MODULAN (available from Amerchol, located in Edison, NJ), OHLAN (available from Amerchol, located in Edison, NJ), petrolatum, phytantriol, and SUPER STEROL ESTERS (available from Croda, located in Parsippany, NJ), or mixtures thereof.

Skin Lightening Agents: Skin lightening agents can actually decrease the amount of  
10 melanin in the skin or provide such an effect by other mechanisms. Skin lightening agents suitable for use herein are described in EP-A-758,882 and EP-A-748,307, both of which are incorporated herein by reference. Further examples of skin lightening agents include adapalene, aloe extract, aminotyrosine, ammonium lactate, anethole derivatives, apple  
15 extract, arbutin, ascorbic acid, ascorbyl palmitate, azelaic acid, bamboo extract, bearberry extract, bletilla tuber, bupleurum falcatum extract, burnet extract, BURNET POWDER (available from Barnet Products, located in Englewood, NJ), butyl hydroxy anisole, butyl hydroxy toluene, chuanxiong, dang-gui, deoxyarbutin, 1,3-diphenyl propane derivatives, 2,5 dihydroxybenzoic acid and its derivatives, 2-(4-acetoxyphenyl)-1,3 dithane, 2-(4-hydroxyphenyl)-1,3 dithane, ellagic acid, escinol, estragole derivatives, esculoside,  
20 esculetin, FADEOUT (available from Pentapharm, located in Basel, Switzerland), fangfeng, fennel extract, gallic acid and its derivatives, ganoderma extract, gaoben, GATULINE WHITENING (available from Gattefosse, located in Saint Priest, France), genistic acid and its derivatives, gentisyl alcohol, glabridin and its derivatives, gluco pyranosyl-l-ascorbate, gluconic acid, glucosamine, glycolic acid, glycyrrhizinic acid, green tea extract, 4-hydroxy-5-methyl-3[2h]-furanone, hydroquinine, 4-hydroxyanisole  
25 and its derivatives, 4-hydroxy benzoic acid derivatives, hydroxycaprylic acid, inositol ascorbate, kojic acid, lactic acid, lemon extract, licorice extract, LICORICE P-TH (available from Barnet Products, located in Englewood, NJ), linoleic acid, magnesium ascorbyl phosphate, MELFADE (available from Pentapharm, located in Basel, Switzerland), MELAWHITE (available from Pentapharm, located in Basel, Switzerland),  
30 morus alba extract, mulberry root extract, niacinamide, nicotinic acid and its esters, nicotinyl alcohol, 5-octanoyl salicylic acid, parsley extract, phellinus linteus extract, placenta extract, pyrogallol derivatives, retinoic acid, retinol, retinyl esters (acetate, propionate, palmitate, linoleate), 2,4 resorcinol derivatives, 3,5 resorcinol derivatives, rose fruit extract, rucinol, salicylic acid, song-yi extract, SOPHORA POWDER (available from Barnet Products, located in Englewood, NJ), 4-thioresorein, 3, 4, 5 trihydroxybenzyl

Englewood, NJ), ELHIBIN (available from Pentapharm AG located in Basel, Switzerland), FLUID OUT COLLOID (available from Vegetech located in Glendale, CA), HYPOTAURINE (available from Sogo Pharmaceutical Co. Ltd located in Chiroda-ku Tokyo), IN CYTE HEATHER (available from Collaborative Labs Inc. located in East Setauket, NY), MICROMEROL (available from Collaborative Labs Inc. located in East Setauket, NY), PEFABLOC SP (available from Pentapharm AG located in Basel, Switzerland), SEPICONTROL AS (available from Seppic located in Paris, France), SIEGESBECKIA (available from Sederma located in Brooklyn, NY), SOPHORINE (available from Barnet Products located in Englewood, NJ), THIOTAIN (available from Barnet Products located in Englewood, NJ), and mixtures thereof.

Skin Tightening Agents: Non-limiting examples of skin tightening agents include BIOCAR SA (available from Amerchol located in Edison, NJ), egg albumen, FLEXAN 130 (available from National Starch located in Bridgewater, NJ), GATULINE LIFTING (available from Gattefosse located in Saint Priest, France), PENTACARE HP (available from Pentapharm AG located in Basel, Switzerland), VEGESERYL (available from Laboratories Serobioloques located in Somerville, NJ), and mixtures thereof.

Anti-Itch Ingredients: Non-limiting examples of anti-itch ingredients include STIMUTEX (available from Pentapharm AG located in Basel, Switzerland), TAKANAL (available from Ikeda-Distributor, located in Tokyo, Japan), ICHTHYOL (available from International Sourcing-Distributor, located in Upper Saddle River, NJ), OXYGENATED GLYCERYL TRIESTERS (available from Laboratoires Seporgia located in Sophia Antipolis, France), and mixtures thereof.

Agents for Inhibiting Hair Growth: Non-limiting examples of suitable agents for inhibiting hair growth include 17 beta estradiol, adamantyguanidines, adamantylamidines, adenylosuccinate synthase inhibitors, anti angiogenic steroids, aspartate transcarbamylase inhibitors, betamethasone valerate, bisabolol, copper ions, curcuma extract, cyclooxygenase inhibitors, cysteine pathway inhibitors, dehydroacetic acid, dehydroepiandrosterone, diopyros leak extract, epidermal growth factor, epigallocatechin, essential fatty acids, evening primrose oil, gamma glutamyl transpeptidase inhibitors, ginger oil, glucose metabolism inhibitors, glutamine metabolism inhibitors, glutathione, green tea extracts, heparin, KAPILANNE (available from International Sourcing Distributor, located in Upper Saddle River, NJ), L, 5 diaminopentanoic acid, L-asparagine synthase inhibitors, linoleic acid, lipoxygenase inhibitors, longa extract, mimosinamine dihydrochloride, mimosine, nitric oxide synthase inhibitors, non steroidal anti-inflammatories, ornithine decarboxylase inhibitors, ornithine aminotransferase inhibitors, panthenol, phorhetur, phosphodiesterase inhibitors, pleione extract, protein kinase C

Humectants can be added to achieve a plasticising effect and to increase the moisturising characteristics of the pre-formed, sheet device when applied to the target surface. Certain humectants such as hexylene glycol may also contribute to the antibacterial properties and characteristics of a pre-formed, sheet device of the present invention. Further, without wishing to be limited by theory, it is thought that incorporating humectants into the pre-

formed, sheet devices of the present invention, increases the stability of the devices such that they are less likely to undergo decomposition under extreme temperature conditions. In general, the pre-formed, sheet devices of the present invention comprise from about 1.0% to about 45%, preferably from about 5% to about 40%, more preferably from about 10% to about 30% by weight of a humectant.

Suitable humectants for use in the present invention are described in WO98/22085, WO98/18444 and WO97/01326, all of which are incorporated herein by reference. Further suitable humectants include amino acids and derivatives thereof such as proline and arginine aspartate, 1,3-butylene glycol, propylene glycol and water and codium tomentosum extract, collagen amino acids or peptides, creatinine, diglycerol, biosaccharide gum-1, glucamine salts, glucuronic acid salts, glutamic acid salts, polyethylene glycol ethers of glycerin (e.g. glycereth 20) glycerin, glycerol monopropoxylate, glycogen, hexylene glycol, honey, and extracts or derivatives thereof, hydrogenated starch hydrolysates, hydrolyzed mucopolysaccharides, inositol, keratin amino acids, LAREX A-200 (available from Larex), glycosaminoglycans, methoxy PEG 10, methyl gluceth-10 and -20 (both commercially available from Amerchol located in Edison, NJ), methyl glucose, 3-methyl-1,3-butandiol, N-acetyl glucosamine salts, panthenol, polyethylene glycol and derivatives thereof (such as PEG 15 butanediol, PEG 4, PEG 5 pentaerythritol, PEG 6, PEG 8, PEG 9), pentaerythritol, 1,2 pentanediol, PPG-1 glyceryl ether, PPG-9, 2-pyrrolidone-5-carboxylic acid and its salts such as glyceryl pca, saccharide isomerate, SEACARE (available from Secma), sericin, silk amino acids, sodium acetylhyaluronate, sodium hyaluronate, sodium poly-aspartate, sodium polyglutamate, sorbeth 20, sorbeth 6, sugar and sugar alcohols and derivatives thereof such as glucose, mannose and polyglycerol sorbitol, trehalose, triglycerol, trimethylpropane, tris (hydroxymethyl) amino methane salts, and yeast extract, or mixtures thereof.

Preferably, the humectants for use herein are selected from glycerine, butylene glycol, hexylene glycol, panthenol and polyethylene glycol and derivatives thereof, or mixtures thereof.

N20" from Croda Chemicals Ltd. (Goole, North Humberside, England). Still other nonionic surfactants are the condensation products of alkylene oxides with both fatty acids and fatty alcohols [i.e. wherein the polyalkylene oxide portion is esterified on one end with a fatty acid and etherified (i.e. connected via an ether linkage) on the other end with a fatty alcohol]. These materials have the general formula  $\text{RCO}(\text{X})_n\text{OR}'$  wherein R and R' are  $\text{C}_{10-30}$  alkyl groups, X is  $-\text{OCH}_2\text{CH}_2-$  (i.e. derived from ethylene glycol or oxide) or  $-\text{OCH}_2\text{CHCH}_3-$  (derived from propylene glycol or oxide), and n is an integer from about 6 to about 100, examples of which include ceteth-6, ceteth-10, ceteth-12, cetareth-6, cetareth-10, cetareth-12, steareth-6, steareth-10, steareth-12, PEG-6 stearate, PEG-10 stearate, PEG-100 stearate, PEG-12 stearate, PEG-20 glyceryl stearate, PEG-80 glyceryl tallowate, PEG-10 glyceryl stearate, PEG-30 glyceryl cocoate, PEG-80 glyceryl cocoate, PEG-200 glyceryl tallowate, PEG-8 dilaurate, PEG-10 distearate, and mixtures thereof.

Other nonionic surfactants that are useful herein are alkyl glucosides and alkyl polyglucosides which are described in more detail in WO98/18444, incorporated herein by reference.

Still other useful nonionic surfactants include polyhydroxy fatty acid amide surfactants, which are described in more detail in WO98/04241.

Other nonionic surfactants suitable for use herein include sugar esters and polyesters, alkoxylated sugar esters and polyesters,  $\text{C}_1\text{-C}_{30}$  fatty acid esters of  $\text{C}_1\text{-C}_{30}$  fatty alcohols, alkoxylated derivatives of  $\text{C}_1\text{-C}_{30}$  fatty acid esters of  $\text{C}_1\text{-C}_{30}$  fatty alcohols, alkoxylated ethers of  $\text{C}_1\text{-C}_{30}$  fatty alcohols, polyglyceryl esters of  $\text{C}_1\text{-C}_{30}$  fatty acids,  $\text{C}_1\text{-C}_{30}$  esters of polyols,  $\text{C}_1\text{-C}_{30}$  ethers of polyols, alkyl phosphates, polyoxyalkylene fatty ether phosphates, fatty acid amides, acyl lactylates, and mixtures thereof. Examples of these non-silicon-containing surfactants include: polysorbate 20, polyethylene glycol 5 soya sterol, steareth-20, cetareth-20, PPG-2 methyl glucose ether distearate, polysorbate 80; polysorbate 60, available under the trade name "Tween 60" from ICI (Wilmington, MA, USA); glyceryl stearate, sorbitan monolaurate, polyoxyethylene 4 lauryl ether sodium stearate, polyglyceryl-4 isostearate, hexyl laurate, PPG-2 methyl glucose ether distearate, and mixtures thereof.

Preferred among the nonionic surfactants are those selected from the group consisting of cetareth-12, sucrose cocoate, steareth-100, polysorbate 60, PEG-60 hydrogenated castor oil, isoceteth-20, oleth-20, PEG-100 stearate, and mixtures thereof.

Other suitable emulsifiers for use herein are polyoxypropylene, polyoxyethylene ethers of fatty alcohols. These materials have the general formula  $\text{R}(\text{CH}_2\text{CHCH}_3\text{O})_x-$



consisting of betaines, sultaines, hydroxysultaines, alkyl sarcosinates (e.g., C<sub>12</sub> - C<sub>30</sub>), and alkanoyl sarcosinates.

The pre-formed, sheet devices of the present invention may optionally contain a silicone containing emulsifier or surfactant. A wide variety of silicone emulsifiers are useful  
5 herein. These silicone emulsifiers are typically organically modified organopolysiloxanes, also known to those skilled in the art as silicone surfactants. Useful silicone emulsifiers include dimethicone copolyols. These materials are polydimethyl siloxanes which have been modified to include polyether side chains such as polyethylene oxide chains, polypropylene oxide chains, mixtures of these chains, and polyether chains  
10 containing moieties derived from both ethylene oxide and propylene oxide. Other examples include alkyl-modified dimethicone copolyols, i.e., compounds which contain C<sub>2</sub>-C<sub>30</sub> pendant side chains. Still other useful dimethicone copolyols include materials having various cationic, anionic, amphoteric, and zwitterionic pendant moieties.

#### Oil Soluble Conditioning Agents

15 The present invention can also optionally comprise oil soluble conditioning agents. Examples of conditioning agents useful as oil soluble conditioning agents include mineral oil, petrolatum, C<sub>7</sub>-C<sub>40</sub> branched chain hydrocarbons, C<sub>1</sub>-C<sub>30</sub> alcohol esters of C<sub>1</sub>-C<sub>30</sub> carboxylic acids, C<sub>1</sub>-C<sub>30</sub> alcohol esters of C<sub>2</sub>-C<sub>30</sub> dicarboxylic acids, monoglycerides of C<sub>1</sub>-C<sub>30</sub> carboxylic acids, diglycerides of C<sub>1</sub>-C<sub>30</sub> carboxylic acids, triglycerides of C<sub>1</sub>-  
20 C<sub>30</sub> carboxylic acids, ethylene glycol monoesters of C<sub>1</sub>-C<sub>30</sub> carboxylic acids, ethylene glycol diesters of C<sub>1</sub>-C<sub>30</sub> carboxylic acids, propylene glycol monoesters of C<sub>1</sub>-C<sub>30</sub> carboxylic acids, propylene glycol diesters of C<sub>1</sub>-C<sub>30</sub> carboxylic acids, C<sub>1</sub>-C<sub>30</sub> carboxylic acid monoesters and polyesters of sugars, polydialkylsiloxanes, polydiarylsiloxanes, polyalkarylsiloxanes, silicone gums e.g. dimethiconol, cyclo-  
25 methicones having 3 to 9 silicon atoms, vegetable oils, hydrogenated vegetable oils, polypropylene glycol C<sub>4</sub>-C<sub>20</sub> alkyl ethers, di C<sub>8</sub>-C<sub>30</sub> alkyl ethers, and mixtures thereof.

These agents are described in more detail in WO98/18444, which is incorporated herein by reference.

#### Thickening Polymers

30 The pre-formed, sheet devices of the present invention can also comprise thickening polymers, preferably from about 0.01% to about 5%, more preferably from about 0.05 to about 3%, and most preferably from about 0.1% to about 2%, by weight of a thickening polymer.

### Other Optional Ingredients

The compositions of the present invention can comprise a wide range of other optional components. These additional components should be pharmaceutically acceptable. The CTFA Cosmetic Ingredient Handbook: Second Edition, 1992, which is incorporated by reference herein in its entirety, describes a wide variety of non-limiting cosmetic and pharmaceutical ingredients commonly used in the cosmetic industry, which are suitable for use in the compositions of the present invention. Non-limiting examples of functional classes of ingredients are described at page 537 of this reference. Examples of these and other functional classes include: abrasives, absorbents, antibiotics, anticaking agents, anti-dandruff agents, anti-perspirant agents, antioxidants, vitamins, biological additives, bleach, bleach activators, brighteners, builders, buffering agents, chelating agents, chemical additives, colorants, cosmetics, cleansers, cosmetic astringents, cosmetic biocides, denaturants, dental treatments, deodorants, desquamation actives, depilatories, drug astringents, dyes, dye transfer agents, enzymes, external analgesics, flavors, film formers, fragrance components, insect repellants, mildewcides, opacifying agents, oxidative dyes, oxidising agents, pest control ingredients, pH adjusters, pH buffers, pharmaceutical actives, plasticizers, preservatives, radical scavengers, skin, hair or nail bleaching agents, skin, hair or nail conditioners, skin, hair or nail penetration enhancers, stabilisers, surface conditioners, reducing agents, temperature depressors, and warmth generators.

Also useful herein are aesthetic components such as colorings, essential oils, and skin healing agents.

Other optional materials herein include pigments. Pigments suitable for use in the compositions of the present invention can be organic and/or inorganic. Also included within the term pigment are materials having a low colour or lustre such as matte finishing agents, and also light scattering agents. Examples of suitable pigments are iron oxides, acyglutamate iron oxides, titanium dioxide, ultramarine blue, D&C dyes, carmine, and mixtures thereof. Depending upon the type of composition, a mixture of pigments will normally be used.

The pH of the sheet devices herein is preferably from about 3 to about 9, more preferably from about 4 to about 8.

The pre-formed, sheet devices of the present invention are patches or masks having a size and shape adapted to conform to the desired target area. The exact size and shape will depend upon the intended use and product characteristics. The pre-formed, sheet devices herein are suitable for topical application to the nails or cuticles, the hair or scalp, a

to reduce evaporative losses. The gel is allowed to solidify undisturbed with cooling to room temperature. The gel is stored at room temperature overnight before readings are taken. The covering is removed and the receptacle with sample tared ( $\pm 0.005\text{g}$ ). Three pieces of filter paper (9.0 cm Whatman-114 Wet Strengthened) are stacked on the flat gel surface. A 9.0 cm diameter flat-bottomed weight of 200 g is placed on the filter paper to ensure close contact with the gel surface. After one minute the weight is removed and filter paper gently peeled away from the gel. The paper should impart a clearly visible matte surface to the gel, which confirms good contact by the filter paper. The sample is reweighed and mass loss calculated by difference. This is reported as grams of exudate released for the 9cm diameter gel disc described above.

#### Gel Compressive Rupture Test

The mechanical properties of the pre-formed, sheet devices of the present invention are measured via compressive failure testing of the gel. The parameters of interest are the gel strength (measured via the compressive force required to rupture a moulded cylinder of gel) and the gel flexibility (measured via the extent of gel compression at the point of rupture). A more detailed description of the test method follows.

Compressive failure testing is performed using a Stable Micro Systems (SMS) Texture Analyser (TA), model TA-XT2i available from Stable Micro Systems Ltd (Godalming, Surrey, UK). The system is controlled through SMS's Texture Expert Exceed software (version 2.03) running within Windows-98. A 100 mm diameter Aluminum compression plate (P-100 probe) is attached to a 50 Kg load cell. This is mounted within the TA Probe Carrier, the extended arm whose vertical travel is under computer control.

To create test samples, a gel formulation of interest is prepared as described below. Gel discs of a precise cylindrical-solid shape (26 mm diameter by 12 mm depth) are formed in moulds. The moulds with sample are hermetically sealed against evaporation during storage. These gel discs are stored at ambient temperature overnight. Each gel disc is removed from its mould just prior to testing and visually inspected for defects. Any gel discs with defects (e.g. trapped air bubbles) are discarded as these defects may impact the measured mechanical properties. The non-defective gel disc is then centered under the P-100 compression plate.

The Texture Expert Exceed software is set-up in Force / Compressive mode. The compression plate is pre-set to a starting height of 12.0 mm. Its rate of descent is set to 0.8 mm/second and total travel distance set to 10.8 mm (i.e. measurement stops when the gel disc is compressed by 90% of its original height). Data is automatically collected on force and position of the compression plate at the rate of 200 pps (points per second). The

Ethyl Paraben	0.1	0.2	0.15	0.1	-	0.1	-
Propyl Paraben	0.05	-	0.05	0.05	-	0.05	-
Disodium EDTA	-	0.1	0.1	0.1	-	0.1	-
Calcium Chloride	-	-	0.08	0.05	-	-	-
Potassium Chloride	-	-	0.5	-	-	-	-
Water	to 100	to 100	to 100	to 100	to 100	to 100	to 100
Exudate Release(g)	0.76	0.89	0.35	0.74	0.83	0.66	0.84
Force To Rupture(N)	78	88	50	67	63	No Rupt.	102
% Compression	58	57	36	41	52	No Rupt.	58
Substrate	Paper <sup>2</sup>	-	-	Non-Woven <sup>3</sup>	-	Non-Woven <sup>3</sup>	

1. Kelgum™ is a 1:1 mixture of xanthan gum and locust bean gum supplied by Kelco, San Diego, CA, USA.

2. "Kimwipes EX-L" available from Kimberley-Clark Corp., Roswell, GA, USA.

3. "Collagen Fiber Mask" available from Beauté Attica, Inc., Redmond, WA, USA.

- 5 The polysaccharide gums are mixed with water to form an uniform dispersion (this can be facilitated by pre-dispersing the polysaccharides in a non-solvent e.g. polyhydric alcohol) and any additional components are added. The mixture is heated with stirring to a first temperature above the gel point of the mixture (ca. 90°C) to fully hydrate the polysaccharide gums. The liquid gel is then dispensed into a suitably shaped mould.
- 10 Preferably, the liquid gel is dispensed via injection moulding. This eliminates any defects which may be introduced by cutting the gel and so improves the robustness of the device. Injection moulding also allows device to be readily formed with varying regions of thickness and other structural features. Alternatively, the liquid gel may be cast into a sheet. The liquid gel is then cooled to a second temperature cooler than the first
- 15 temperature at or below the gel point of the mixture (e.g. ambient temperature) to set up the gel structure. The device may then be removed from the mould or appropriately shaped patches may be cut from the gel sheet. The devices herein are then packaged into materials which have low water vapour permeability to minimise drying out of the device during storage. Suitable packaging for devices herein include sachets or sealed trays. If
- 20 the device is packaged in a sachet, it is preferably protected prior to use. This protection can be provided by a release liner such as a plastic film, which provides easy release for the device.

**CLAIMS**

1. A pre-formed, sheet device comprising;
  - (a) less than 10% of a polysaccharide mixture consisting of;
    - (i) a red seaweed polysaccharide;
    - (ii) a mannose containing polysaccharide selected from a galactomannan, glucomannan, and derivatives or mixtures thereof and;
    - (iii) a fermentation polysaccharide, or derivatives thereof; and
  - (b) from about 30% to about 99.5% of water;wherein the device comprises less than 10% total polysaccharide.
2. A pre-formed, sheet device according to Claim 1 wherein the red seaweed polysaccharide is selected from agar, agarose, kappa-carrageenan and furcellaran, or mixtures thereof.
3. A pre-formed, sheet device according to any of Claims 1 to 2 wherein the red seaweed polysaccharide is selected from agar and agarose, or mixtures thereof.
4. A pre-formed, sheet device according to any of Claims 1 to 3 wherein the galactomannan is selected from locust bean gum, guar gum, and cassia gum, or mixtures thereof.
5. A pre-formed, sheet device according to any of Claims 1 to 4 wherein the glucomannan is selected from konjac mannan and deacetylated konjac mannan, or mixtures thereof.
6. A pre-formed, sheet device according to any of Claims 1 to 5 wherein the fermentation polysaccharide, or derivatives thereof is selected from xanthan gum and gellan gum, or mixtures thereof.
7. A pre-formed, sheet device according to any of Claims 1 to 6 which comprises less than 5% of the polysaccharide mixture.
8. A pre-formed, sheet device according to any of Claims 1 to 7 wherein the ratio of red seaweed polysaccharide to mannose containing polysaccharide is from 20:1 to about 1:5.
9. A pre-formed, sheet device according to any of Claims 1 to 8 wherein the ratio of red seaweed polysaccharide to mannose containing polysaccharide is from about 7:1 to about 1:2.

# INTERNATIONAL SEARCH REPORT

Int. Application No.

PCT/US 00/09693

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C08L5/00 A61L15/06 A61K9/06 A61K7/48 A61K9/70

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C08L A61K A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, PAJ

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 219 803 A (MERCK & CO INC) 20 December 1989 (1989-12-20) page 2, line 9 - line 22	1-14
X	PATENT ABSTRACTS OF JAPAN vol. 9, no. 12 (C-261), 18 January 1985 (1985-01-18) & JP 59 162847 A (SANEI KAGAKU KOGYO KK), 13 September 1984 (1984-09-13) abstract & DATABASE WPI Week 198425 Derwent Publications Ltd., London, GB; AN 266551 abstract	1-14

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
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- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

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# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 00/09693

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